August 27, 2025

San Diego BioMed

Date: Aug 27, 2025

Location: Zoom Meeting

Chair: Sylvie Blondelle

Attendees: Committee members including Sylvie Blondelle, Roberto Baccala, James Binley, Emma Crook (new member), Grishma Acharya (new member)

Clara Szeto was absent.

1. **Update on IBC Roster.**

The Chair opened the meeting, welcomed all members, and noted the addition of Emma and Grishma to the committee.

2. **Approval of IBC meeting minutes from December 17, 2024**

The minutes from December 17, 2024, were displayed and reviewed; no corrections were requested, a motion was made and seconded, and the minutes were approved.

3. **NIH transparency and minutes format**

The committee discussed NIH expectations to post minutes publicly and to include clearer protocol summaries, risk assessments, training and biosafety levels. Going forward, minutes will capture protocol title, concise summary, agent or source, risk assessment, training, biosafety level, committee discussion, and decision.

4. **Protocol reviews**

New registration:

Principal Investigator: Maria Cecilia Marcondes
Protocol #: rDNA-25-001-MCM
Title: Methamphetamine, HIV integration and latency in the brain
Project summary (from form): Study modifiers of HIV integration.
Additional details from the protocol: This study will use a reporter (GFP or luciferase) tagged pseudovirus that can infect but is not able to replicate.
Source of nucleic sequences (e.g., species): Synthetic
Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene): viral proteins, fluorescent protein
Host(s) and Vector(s): Human cells
Risk Assessment: Low
Training: Verified and on record

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Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2 with BSL-3 practices aimed at containing the aerosols
CA ATP-L : Yes
NIH Guidelines: III-D
Category 1 Research: No
Category 2 Research: No
Discussion: The PI was asked to provide clarity on the following: 1. The host strain; 2. Source of the nucleic acid sequences; 3. Expend on the summary of overall goals of proposed research.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Principal Investigator: Richard Milner
Protocol #: BHR-25-002-RM
Title: Evaluating integrin expression in human brain samples
Project summary (from form): The goal of this project is to define the expression pattern of specific integrins in blood vessels and microglia in postmortem samples of human brain. We are particularly interested in studying the integrin expression pattern on microglia in human brain tissue to ascertain if it corresponds to what we observe in rodent brain tissue. In addition, the samples provided are 4 normal controls with 4 samples where advanced vascular inflammation and artherosclerosis have been detected, which will allow us to determine if microglia (and blood vessels) show inflammation-associated changes in integrin expression on microglia and vascular cells.
Agent: Human brain tissue
Additional details from the protocol: The cells will be purchased from vetted repositories
Manipulations planned: cryostat, microscopy
Recombinant or synthetic nucleic acid molecules: None
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human material
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Cryostat sectioning does not require a biosafety cabinet, but standard practices apply. Requested corrections include specifying the agent as postmortem human brain tissue, confirming personnel training and initials, marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

IBC Approval:

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The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Three-year rewrite:

Principal Investigator: David M. Gilbert
Protocol #: rDNA-25-001-DMG
Title: cis-Acting Elements Regulating Developmental Control of Replication Timing, Computational Methods for Next-Generation Comparative Genomics
Project summary (from form): We are making deletions/insertions to investigate cis-acting DNA elements regulating developmental control of replication timing or genome 3D structure. We also introduce degron tags to the candidate proteins to see the effect of knockdown of the protein on replication timing or genome 3D structure.
Additional details from the protocol: Cell lines will be engineered using Cas9 in combination with guide RNA. The effect of engineering in replication timing or nuclear compartmentalization by repli-seq and other genomics analysis.
Source of nucleic sequences (e.g., species): Synthetic
Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene): Guide RNA, enzyme, fluorescent proteins
Host(s) and Vector(s): Established rodent and human cells
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: III-E
Category 1 Research: No
Category 2 Research: No
Discussion: No viral vectors are used. Corrections were requested to mark vector related questions as “not applicable”.
IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Principal Investigator: David M. Gilbert
Protocol #: BHR-25-001-DMG
Title: Chromosome Replication and Epigenome Regulation in Mammalian Cells
Project summary (from form): The goal of this project is i) to reveal mechanisms by which perturbation of cancer-relevant cellular pathways produce unique patterns of fragile sites in cell culture and match these patterns to specific cancer types; ii) to identify mechanisms by which ERCEs coregulate RT, chromatin architecture and transcription; iii) to in vitro differentiate then produce and analyze genomics data from various cell lines; iv) to develop a tool to detect the 3D

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architecture of replisomes in living cells and their responses to stress; and v) to provide various genomics data from cell lines to computational labs.
Agent: Established human cell lines and primary human cells.
Additional details from the protocol: The cells will be purchased or received from vetted repositories and centers.
Manipulations planned: Pipetting, tissue culture, centrifugation, flow cytometry, HPLC/FPLC, spectrophotometry
Recombinant or synthetic nucleic acid molecules: None
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Requested corrections: 1. Indicating human cells as potential pathogens to human and checking Skin Absorption and Inoculation as potential route of exposure; 2. Identifying centrifugation as an aerosol generating procedure; 3. Clarifying if cells are already in the lab; 4. Updating personnel involved in the project; 5. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization; 6. Indicating that entry into tissue culture rooms must require at least lab coat and gloves for all individuals including observers.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Annual renewal:

Principal Investigator: Charles D. Murin
Protocol #: rDNA-24-001-DMC
Title: HIV antibodies and NK cell ADCC: nanometer scale tracking of immune synapse dynamics
Project summary (from form): The goal is to better understand the molecular mechanisms that drive antibody-ba effector functions, specifically how Natural Killer (NK) cells perform antibody dependent cellular cytotoxici (ADCC) on virally infected cells. Target cell line expressing viral proteins on their cell surface will be generated using the PiggyBac system. We will also produce NK cell lines that express the IgG1 receptor CD16, along with versions that have tags to label this protein with a fluorescent tag. We will be using target cells lines to complete in vitro ADCC assays, and we will also observe NK cells during ADCC using fluoromicroscopy techniques.
Additional details from the protocol: No viral vectors are used.
Source of nucleic sequences (e.g., species): Human and viruses
Nature of nucleic acid (NA) sequences (e.g., enzyme, oncogene): receptor, viral proteins, immunoglobins

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Host(s) and Vector(s): Established rodent and human cells
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: III-D2
Category 1 Research: No
Category 2 Research: No
Discussion: This annual renewal reported no protocol changes other than updates to personnel.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels.

Principal Investigator: Charles D. Murin
Protocol #: BHR-24-001-DMC
Title: Mechanisms of Natural Killer cell mediated ADCC
Project summary (from form): The goal of this project to acquire a more detailed understanding of how antibodies recruit Fc mediated cellular activity and to develop novel strategies to engineer treatments that can recruit specific effector functions with maximal potency in vivo.
Agent: Human cell lines, PBMCs, and blood.
Additional details from the protocol: The cells will be purchased or received from vetted repositories and centers.
Manipulations planned: Pipetting, tissue culture, centrifugation, shaking, flow cytometry, HPLC/FPLC, spectrophotometry
Recombinant or synthetic nucleic acid molecules: None
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Requested corrections: 1. Indicating human cells as potential pathogens to human and checking Skin Absorption and Inoculation as potential route of exposure; 2. Identifying centrifugation as an aerosol generating procedure; 3. Clarifying if cells are already in the lab; 4. Correcting date of hiring and/or immunization of personnel involved in the project; 5. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modification discussed.

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Principal Investigator: Joanna Davies
Protocol #: BHR-23-002-JD
Title: A study to identify immunological markers to predict/monitor disease progression in patient populations with chronic disorders
Project summary (from form): The goal of this project is to better understand the T cell immune response in type 1 diabetes progression to develop biomarkers for prognosis and prediction, as well as therapies to treat, delay, or prevent the disease.
Agent: Human plasma, PBMCs, and blood.
Additional details from the protocol: The cells will be received from vetted repositories and centers.
Manipulations planned: Pipetting, tissue culture, centrifugation, sonicating, flow cytometry, spectrophotometry
Recombinant or synthetic nucleic acid molecules: None
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human cells
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Requested corrections: 1. Transferring the summary of the project from the original protocol; 2. Indicating that it is not a transforming agent and no lab testing/blood sampling is done prior working with the agent materials; 3. Marking risk to immunosuppressed personnel as unknown, and naming hepatitis B immunization.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Principal Investigator: Richard Milner
Protocol #: BHR-24-001-RM
Title: Evaluating the protective roles of mild hypoxia and integrins in inflammatory demyelinating disease
Project summary (from form): The goal of this project is to define the optimal dose of the hypoxia mimetic FG-4592 in the EAE model and then evaluate the role of HIF1α and HIF-2α-mediated vascular remodeling in conferring this protection. The protocol to induce disease in the chronic progressive EAE model requires in vivo intraperitoneal injections of pertussis toxin.
Agent: Pertussis toxin
Additional details from the protocol: The toxin will not be stored but purchased as part of the kit for each experiment.
Manipulations planned: Pipetting, injecting, microscopy
Recombinant or synthetic nucleic acid molecules: None

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Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Pertussis immunization
Assigned Biosafety Level: BSL-2
CA ATP-L : No
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Requested corrections: 1. Indicating that no lab testing/blood sampling is done prior working with the agent materials; 2. Adding the initials of personnel involved in the project.

IBC Approval:
The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

Principal Investigator: Maria Cecilia Marcondes
Protocol #: BHR-24-001-MCM
Title: Deciphering Drivers of Chronic COVID Syndrome
Project summary (from form): The goal of this project is to understand a new health condition that is prevalent in the growing 2019 SARS CoV-2 (COVID19) convalescent population, known as PASC (Post-Acute sequelae of COVID). PASC is detectable based on a diversity of symptoms, including but not restricted to cardiovascular, gastrointestinal and neurological, which could result from unmasking underlying co-morbidities, residual damage from acute infection or persistent immune activation. In this study we will develop a panel of peripheral biomarkers that can be combined with clinical and structural measures to increase fill the gap of knowledge about this novel disease while offering a complete assessment of the symptoms etiology and to aid in the identification of risk factors and potential therapeutic strategies.
Agent: Blood from long COVID patients
Additional details from the protocol: The blood is received from the Huntington Hospital, samples are covered and approved by the Institute IRB.
Manipulations planned: Pipetting, injecting, microscopy
Recombinant or synthetic nucleic acid molecules: None
Risk Assessment: Low
Training: Verified and on record
Occupational Medicine: Hepatitis B immunization for working with human material
Assigned Biosafety Level: BSL-2 with BSL-3 practices aimed at containing aerosols
CA ATP-L : Yes
NIH Guidelines: n/a
Category 1 Research: No
Category 2 Research: No
Discussion: Personnel lists and biosafety cabinet certification must be updated.

IBC Approval:

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The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.
Principal Investigator: Maria Cecilia Marcondes **Protocol #:** BHR-23-001-MCM **Title:** Metamphetamine abuse and immune system interactions in neuroAIDS **Project summary (from form)**: The goal of this project is to examine the hypothesis that Methamphetamine exposure aggravates molecular changes that happen as a result of viral infection in innate immune cells that are derived from the brain. Methamphetamine will be added to innate immune cell lines, human macrophages, and latently infected U1 macrophages, together with different non-infectious peptides, for the examination of molecular phenotypes that are triggered by those interactions. **Agent**: Blood, brain tissue, peripheral blood cells and cell lines **Additional details from the protocol**: The samples are commercially available or from vented repositories. **Manipulations planned**: Pipetting, centrifuging, flow cytometry **Recombinant or synthetic nucleic acid molecules**: Pseudoviruses covered under Protocol: rDNA-25-001-MCM **Risk Assessment:** Low **Training:** Verified and on record **Occupational Medicine:** Hepatitis B immunization for working with human material **Assigned Biosafety Level:** BSL-2 **CA ATP-L** : No **NIH Guidelines:** n/a **Category 1 Research:** No **Category 2 Research:** No **Discussion**: Personnel lists and biosafety cabinet certification must be updated. Inhalation as a potential route of transmission for this agent needs to be marked. They need to clarify what the hypothesis is with latency. **IBC Approval:** The protocol was unanimously approved at the current biosafety levels, with the modifications discussed.

5. Proposed revised SOPs

The committee reviewed updates required by federal policy changes including new categories one and two and the concept of pathogens with enhanced pandemic potential. SOPs were revised accordingly. Application forms were reorganized to begin with agent information followed by project information, storage and use, decontamination and disposal, personnel and training, biosafety practices, and emergency procedures. Non applicable fields were added.

Immunization entries will specify vaccine names when marked yes. The committee agreed that approvals will be recorded as by majority unless otherwise specified.

a. Policy on Research Involving Recombinant or Synthetic Nucleic Acid Molecules and Biohazardous Materials
b. IBC Review Procedures
c. IBC Policy and Procedures on Dual Use Research of Concern and Pathogen of Enhanced Pandemic Potential

6. **NIH Reportable Incidents**: None

7. **DURC/PEPP**: None

8. **Next meeting and adjournment**

No additional question was raised. The next meeting is tentatively planned for January or February. Celine will confirm availability. The meeting was adjourned at 12:56 PM with thanks to all participants.